

REMARKS

The Final Office Action of October 9, 2008, has been received and reviewed. All claims stand rejected. Applicants respectfully request amendment of the claims as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 27, 48, 50 and 51 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Ivanov *et al.* (hereinafter “Ivanov”) in view of Werner *et al.* (Expereintia Vol. 42, 521-531, 1986) (hereinafter “Werner”) in view of Cillari *et al.* (Infection and Immunity, VOI 62, No. 6, p. 2649-2652, June 1994) (hereinafter “Cillari”) in view of Lam *et al.* (U.S. Pat. 5,650,489) (hereinafter “Lam”) in view of Houghten *et al.* (DDT, Vol. 5, No. 7, 276-285, July 2000) (hereinafter “Houghten”) in view of Lin *et al.* (U.S. Pat. Pub. 2002/0147306) (hereinafter “Lin”) (collectively hereinafter “the references”). Applicants respectfully traverse the rejections as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id* at 1741, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed To facilitate review, this analysis should be made explicit.” *Id*. Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of

success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

Applicants respectfully submit that the references cannot render obvious the methods of amended claims 27 and 50 as the references or the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention do not teach or suggest the claim elements of amended claims 27 and 50. Specifically, the references do not teach or suggest “determining the identity of a peptide compound that modulates an activity selected from the group consisting of development of the systemic inflammatory response, regulation of members of the nuclear factor- κ B family, accentuation of sepsis or protection from sepsis, nitrate production, and combinations thereof,” as recited by amended claims 27 and 50. While Werner and Ivanov may teach or suggest activity for hemoglobin fragments, Tuftsin, TKP, FDP, and casein fragments, Werner and Ivanov do not teach that these fragments have activity for the “development of the systemic inflammatory response, regulation of members of the nuclear factor- κ B family, accentuation of sepsis or protection from sepsis, nitrate production, and combinations thereof” as recited by amended claims 27 and 50. In addition, applicants respectfully submit that the remainder of the references do not remedy these deficiencies in Ivanov and Werner. Consequently, the references cannot render obvious amended claims 27 and 50 as the references do not teach or suggest all of the claim elements of amended claims 27 and 50.

Moreover, applicants respectfully submit that one of ordinary skill in the art, with knowledge of the references, would have had no reasonable expectation of success in identifying peptides that modulate development of the systemic inflammatory response, regulation of members of the nuclear factor- κ B family, accentuation of sepsis or protection from sepsis, nitrate production, and combinations thereof as indicated by amended claims 27 and 50. None of the references cited indicates that such peptides have the ability to modulate these activities; thus, one of ordinary skill in the art could not have had a reasonable expectation of success in identifying peptides with these properties.

Furthermore, no apparent reason exists to combine the known elements in the fashion claimed herein. While the references indicate the peptides with specific activities have been identified, no indication or reason exists to believe that small peptides could have activities such

as modulating the development of the systemic inflammatory response, regulation of members of the nuclear factor- κ B family, accentuation of sepsis or protection from sepsis, nitrate production, or combinations thereof. Further edifying this analysis, applicants respectfully submit that no teaching, suggestion, or motivation is identified in the references or the knowledge of one of ordinary skill in the art to search for peptides with the activities recited in claims 27 and 50. Consequently, there would have been no apparent reason for one of ordinary skill in the art to combine the reference to arrive at the presently claimed methods.

Also, the references do not indicate that the methods of amended claims 27 and 50 would be obvious to try within the scope of 35 U.S.C. § 103(a). While one could have tried all peptides of 3 or 4 amino acids in length in a screen against the modulation of any conceivable biological process, the numbers of possible peptides, combined with the number of possible biological processes one could test for, leaves the realm of the finite number of predictable solutions that are required to sustain an objection under the obvious to try rationale. *KSR*, 127 S.Ct. at 1742. Further none of the solutions is predictable given that molecular biology is considered an unpredictable art *per se* and that peptides capable of modulating the development of the systemic inflammatory response, regulation of members of the nuclear factor- κ B family, accentuation of sepsis or protection from sepsis, nitrate production, or combinations thereof have not been identified in the prior art cited by the Office. Thus, without a finite number of predictable solutions, the methods of amended claims 27 and 50 cannot be considered obvious under 35 U.S.C. § 103(a) as obvious to try.

For at least the foregoing reasons, applicants respectfully request the withdrawal of the rejections of claims 27 and 50 under 35 U.S.C. § 103(a) and reconsideration of same.

In addition, applicants respectfully submit that claims 48 and 51 cannot be considered obvious in view of the references, *inter alia*, as these claims each depend from one of non-obvious claims 27 and 50. As such, applicants respectfully request the withdrawal of the rejections of claims 48 and 51 under 35 U.S.C. § 103(a) and reconsideration of same.

ENTRY OF AMENDMENTS

Pursuant to 37 C.F.R. § 1.116, applicants respectfully submit that the amendments presented herein should be entered as the amendments are made to expedite prosecution, are

believed to remove issues for appeal, and place the application in condition for allowance.

Applicants respectfully note that, as indicated at MPEP § 714.13(III), the Examiner is required to give the proposed amendments sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Applicants respectfully submit that the amendments avoid the rejections set forth in the Final Office Action, raise no issues of new matter, present no issues requiring further consideration or search, and do not present any additional claims. If the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested as they remove issues for appeal. As such, the applicants respectfully request that the amendments presented herein be entered and a Notice of Allowance issued.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Daniel J. Morath', with a stylized flourish at the end.

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